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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,009	08/06/2002	Carolyn K. Goldman	NIH-05111	5287

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/089,009	Applicant(s) GOLDMAN ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3-5,9-15,22 and 23*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). ____
13. ☐ Other: _____.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Continuation of 3. NOTE: the newly added claims 24 and 25 raise a new issue that would requires further consideration and new ground of rejection. Claims 24 and 25 recite a molecular weight of 32,000 to 34,000, and 26,000 to 28,000, respectively, which require further evaluation. Further the claims would be rejected under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160), for the same reasons in the prior art rejection of claims 1, 3-5, 9, 10, 13-15, 22 and 23 set forth in the previous Office Actions. Therefore, the proposed amendment does not place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Further, the new claims 24 and 25 present additional claims without canceling a corresponding number of finally rejected claims as only claim 10 is canceled in the instant response.

Continuation of 11. does NOT place the application in condition for allowance because:
Claims 9-15 remain rejected under 35 U.S.C. 112, second paragraph, for the reasons of records set forth in the previous Office Actions mailed on 4/19/05.

Applicants argue, on page 6 of the response, that claim 9 has been amended to include the method steps (a)-(c). Applicants argument has been fully considered, but is not deemed persuasive because, as addressed in the last Office Action mailed on 6/3/04, claim 9 is still incomplete for omitting essential method steps of the process. The preamble of the claim recites "a method for purifying ...", whereas the method steps are merely up to forming a complex (step (c)), which is not complete, nor sufficient to allow the achievement of the goal for purifying the polypeptide set forth in the preamble.

Claims 1, 3-5, 9, 10, 13-15, 22 and 23 remain rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160), for the reasons of record set forth in the previous Office Actions.

The Declaration by Dr. Waldmann under 37 CFR 1.132 filed on 17 June 2005 is insufficient to overcome the prior art rejection of claims 1, 3-5, 9, 10, 13-15, 22 and 23 based upon Colamonici et al. (J. Immunol., 1990, 145:155-160) under 35 U.S.C. 102(b), or, in the alternative, under 35 U.S.C. 103(a) as set forth in the last Office action because for the following reasons.
The Declaration indicates that the Colamonici reference discloses the use of mAb anti-Tac and 7G7/B6 (both recognize epitopes of the a chain of IL-2R) to immunoprecipitate IL-2Ra and polypeptides associated therewith, including the 37 kDa and 20 kDa polypeptides, whereas the inventors of the instant application demonstrates that when cell lysates are first pre-cleared with anti-Tac to remove all components which may bind to the anti-Tac antibody, and then are immunoprecipitated with the 5F7 antibody (recognizing the two polypeptides of the present invention), demonstrating that the 32-34 kDa and 26-28 kDa ILRAPs of the present invention are not recognized by the anti-Tac mAb in the pre-clearing step (items 4-6). The declaration further indicates that the presence of ILRAPs can be demonstrated in a particular cell line where IL-2Ra is not expressed, and therefore, these polypeptides cannot be recognized by anti-Tac and 7G7/B6 mAb, but are recognized by the 5F7 mAb, indicating that Colamonici's polypeptides are not capable of forming a complex with the 5F7 (item 7). These are not persuasive because, with respect to applicants demonstration that the 32-34 kDa and 26-28 kDa ILRAPs of the present invention are not recognized by the anti-Tac, it is irrelevant because nowhere in the Colamonici reference indicates that the 37 kDa and 20 kDa polypeptides are recognized by anti-Tac mAb neither, and the pre-clearance with anti-Tac would not eliminate possible free form of the polypeptides that were not associated with the IL-2Ra at the time the pre-clearing step occurred. Further, with respect to applicants conclusion that Colamonici's polypeptides are not capable of forming a complex with the 5F7, it is unclear based on what such a conclusion could be drawn as neither the applicant nor Colamonici has ever tested such, or provided any relevant information regarding such. Further, the declaration provides no actual experimental evidence such that the examiner can independently draw conclusions. Therefore, the declaration is insufficient to overcome the instant rejection.

Applicants argument in the response based on the same declaration has been fully considered, but is not deemed persuasive for the same reasons above.